AMENDMENT UNDER 37 C.F.R. § 1.111

Application No.: 10/538,758

REMARKS

Claims 1, 6, 8, 10, 17, 19, 23, 28 and 33 are amended. Claims 2-5, 7, 11-16, 18, 20-22, 24-27, 31-32 and 34 are canceled. Support for the amendments to the claims is found, for example, in the original claims. No new matter is presented.

I. Election/Restriction

The Examiner has acknowledged Applicant's election to prosecute Group I directed to claims 1-34 wherein A is an azepane ring and B is a pyrimidine ring, filed on December 28, 2007, in response to the Examiner's restriction requirement.

II. Priority

In paragraph 2 of the Action the Examiner indicates that the priority date of the present application is June 10, 2005, allegedly because the PCT application to which priority is claimed was not published in English.

Applicants respectfully submit that the Examiner is incorrect. The present application is the National stage entry of PCT/JP03/15718 filed December 9, 2003, and the filing date of the National stage application is the same as the filing date of the international application. See MPEP § 201.13(b) and MPEP§1893.03(b). Thus, the effective filing date of the present National stage application is December 9, 2003. There is no requirement that the PCT application to which the present application claims priority be published in English to claim the benefit of priority to the international application.

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Applicants also submit that the present application is entitled to a priority date of December 10, 2002 and January 6, 2003 based on JP Patent Application Nos. 2002-357446 and 2003-162706, respectively.

III. Response to Objection to the Specification

In paragraphs 3-4 of the Action, the Examiner objects to the specification as improperly incorporating essential material by reference with respect to the CCR2, CCR3, CCR4 and CCR5 antagonists recited in claim 28. Specifically, the Examiner states that various WO applications are mentioned in the specification at page 70 for examples of the CCR2, CCR3, CCR4 and CCR5 antagonists recited in claim 28.

Claim 28 is amended herein by deleting the recitations of CCR2, CCR3, CCR4 and CCR5 antagonists, thereby obviating the objection to the specification since the description in the specification is not essential material to the subject matter of amended claim 28.

Accordingly, withdrawal of the objection to the specification is respectfully requested.

IV. Response to Claim Objections

In paragraph 5, claims 1-8, 10-18, 20-31 and 33-34 are objected to by the Examiner as containing non-elected subject matter.

The claims are amended herein to delete non-elected subject matter, thereby obviating the objection to the specification.

Accordingly, Applicants respectfully request withdrawal of the objection to the claims.

V. Claim Rejections Under 35 U.S.C. § 112, 1st Paragraph

A. "N-Oxides", "solvates", "prodrugs"

In paragraph 7, claims 1-31, 33 and 34 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for salts of formula I, allegedly does not reasonably provide enablement for N-oxides, solvates and prodrugs of formula I.

The claims are amended herein by deleting the recitations of N-oxides, solvates and prodrugs, thereby obviating this rejection.

B. "prevention"

In paragraph 8, claims 33 and 34 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for <u>treatment</u> of disorders listed in claims 33 and 34, allegedly does not reasonably provide enablement for <u>prevention</u> of disorders listed in claims 33 and 34.

Claim 33 is amended by deleting the recitation of "preventing and/or" and claim 34 is canceled, thereby obviating this rejection.

C. Written description

In paragraph 10, claims 1-8, 10-31, 33 and 34 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. More specifically the Examiner asserts that based on the analysis of formula (I), there is no common core because each of the meanings of variables A, B and Y are very broad.

The claims are amended herein by further defining the substituents based on compounds in the examples of the specification, thereby obviating this rejection.

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In view of the above, withdrawal of the §112, first paragraph, rejections is respectfully requested.

VI. Response to Claim Rejections under 35 U.S.C. § 112, 2nd Paragraph

- A. In paragraph 12, claims 1-31, 33 and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- (1). The Examiner states that the terms "an amino group which may be protected", "a hydroxyl group which may be protected", and "a mercapto group which may be protected" are indefinite.
- (2) The Examiner also states that claim 34 is indefinite as to what specific disorders are meant by each of the following terms: inflammatory diseases, immune diseases, allergic diseases, infectious diseases, diseases accompanied with HIV infection, psychoneurotic diseases, cerebral disease, cardiovascular disease, metabolic diseases and cancerous diseases.

Regarding paragraph (1) the terms "an amino group which may be protected", "a hydroxyl group which may be protected", and "a mercapto group which may be protected" are deleted from the claims, thereby obviating this aspect of the rejection.

Regarding paragraph (2), claim 34 is canceled, thereby obviating this aspect of the rejection.

B. In paragraph 13, claims 8, 17 and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements, such as the meanings of the L and Q variables in claims 8 and 19 and the meanings of A, B and Y in claim 17.

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Claims 8 and 19 are amended by inserting the definitions of the L and Q variables and claim 17 is amended by inserting the definitions of A, B, and Y, thereby obviating this aspect of the rejection.

C. In paragraph 13 of the Action, claim 33 is said to be unclear as to its intended scope in view of the recitation of "claim language reciting inhibitory activity".

Applicants respectfully traverse the rejection as applied to claim 33 as claim 33 is directed to a method of treatment of HIV infection and does not have "claim language reciting inhibitory activity" regarding "CXCR4". It is considered that the Examiner intended to refer to claim 31, which recites "a method of antagonizing CXCR4 in a mammal". Claim 31 is canceled herein.

D. In paragraph 14 of the Action, claims 5 and 6 are said to be indefinite because there is insufficient antecedent basis for the recitation of variable J in the claims.

Claim 1 is amended by incorporating subject matter from claim 5 and claim 5 is canceled.

Claim 6 is amended to depend from amended claim 1.

In view of the above, withdrawal of the §112, 2nd paragraph, rejections is respectfully requested.

VII. Response to Claim Rejections Under 35 U.S.C. § 102

Claims 1-3, 10-18 and 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Arnaiz et al (WO 98/37079).

Claims 1-3, 7-8, 10-16 and 19-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nuss et al (WO 2004/048365).

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Claims 1-3 and 17-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Postovskii et al (see STN search report).

Claims 1-6, 10-18, 25-27, 31, 33 and 34 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nishizawa et al (WO 2004/080966).

First, Applicants note that Nuss et al (WO '365) does not qualify as a reference under 35 U.S.C. § 102(b) as indicated by the Examiner, since the publication date of June 10, 2004 of the reference is after the effective filing date of December 9, 2003 of the present application as discussed in section II above.

Nuss et al does qualify as a reference under 35 U.S.C. § 102(e) based on its international filing date of November 21, 2003 and the filing dates of Provisional App. Nos. 60/428,473, 60/438,568 and 60/523,081 of November 21, 2002, January 7, 2003 and November 19, 2003, respectively. Applicants claim priority to JP 2002-357446 and submit a sworn English translation of the priority document filed December 10, 2002, which antedates the international filing date of Nuss et al and the provisional applications except for the '473 provisional application. However, the '473 provisional application does not disclose compound 51¹ relied on by the Examiner at page 70 of the WO '365 publication of Nuss et al.

In view of the above, the WO '365 publication of Nuss et al is removed as §102(e) prior art with respect to the international filing date and the '568 and '081 provisional applications. Further, the '473 provisional application fails to disclose compound 51 relied on by the

¹ The Examiner states that compound 50 at page 70 of the WO '365 publication anticipates the present claims; however, Applicants believe that the Examiner made an error because compound 50 does not include an azepane ring. Applicants consider that the Examiner intended to refer to compound 51 at page 70 of the reference instead.

Examiner and therefore the WO '365 publication is not legally effective prior art with respect to the present application.

Also, Nishizawa et al (WO '966) does not qualify as prior art against the present application since it was published September 23, 2004 after the effective filing date of the present application of December 9, 2003 based on the filing date of the international application as discussed in section II above.

Independent claim 1 is amended by incorporating the subject matter of claim 4, which is not included in the rejections based on Arnaiz et al and Postovskii et al.

Independent claim 8 is not included in the rejections based on Arnaiz et al, Postovskii et al.

Claims 10 and 17 recite compounds having the same scope as represented by formula (I) as recited in amended claim 1 and are distinguished over the art for at least the same reasons.

Claim 23 depends from claim 8 and is distinguished over the art for at least the same reasons.

Claims 2, 3, 7, 11-16, 18, 20-22 and 24-27 are canceled, thereby rendering the rejections of these claims moot.

Accordingly, Applicants respectfully request withdrawal of the §102 rejections.

VIII. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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